IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KING PHARMACEUTICALS, INC. and MERIDIAN MEDICAL TECHNOLOGIES, INC., Plaintiffs, v. TEVA PARENTERAL MEDICINES, INC., and TEVA PHARMACEUTICALS USA, INC., Defendants.	Civil Action No. 09 CV 652 (SLR) **JURY TRIAL DEMANDED**

DEFENDANTS TEVA PARENTERAL MEDICINES, INC.'S and TEVA PHARMACEUTICALS USA, INC.'S, ANSWER AND AFFIRMATIVE DEFENSES

Defendants Teva Parenteral Medicines, Inc. ("TPM") and Teva Pharmaceuticals USA, Inc. ("Teva USA") (collectively "Defendants" or "Teva") by and through the undersigned attorneys, answers the Complaint of Plaintiffs King Pharmaceuticals, Inc. ("King") and Meridian Medical Technologies ("Meridian") (collectively "Plaintiffs") as follows:

NATURE OF THE ACTION

1. Defendants admit that Plaintiffs' Complaint is for patent infringement of U.S. Patent No. 7, 449,012 B2 ("the '012 patent") under the patent laws of the United States, but deny that Plaintiffs are entitled to such relief. Defendants admit that TPM filed Abbreviated New Drug Application ("ANDA") No. 90-589 with the United States Food and Drug Administration ("FDA") to obtain approval to manufacture and sell TPM's Epinephrine Injection, USP Auto-Injector, 0.15 mg and 0.3 mg ("TPM's product") prior to the expiration of the '012 patent. Defendants admit that the '012 patent is listed in the FDA's Orange Book and

that according to the FDA's records the '012 patent will expire on September 11, 2025. Defendants deny any remaining allegations in paragraph 1.

THE PARTIES

2 On information and belief, Defendants admit that King is a Tennessee corporation with its principal place of business at 501 Fifth Street, Bristol, Tennessee 37620. On information and belief, Defendants admit that King manufactures pharmaceuticals. Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and, therefore, deny the same.

3. On information and belief, Defendants admit the allegations of paragraph 3.

4. Defendants admit that the FDA lists Meridian as the holder of approved New Drug Application ("NDA") No. 019-430 for EpiPen® (epinephrine) Auto-Injector 0.3/0.15 mg, sold under the name EpiPen® Auto-Injector. Defendants further admit that the '012 patent is listed in the FDA's Orange Book in connection with NDA No. 019-430. Upon information and belief, Defendants admit that the EpiPen® Auto-Injector is a disposable drug delivery system manufactured by Meridian and sold throughout the United States and worldwide. Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and, therefore, deny all remaining allegations of paragraph 4.

5. Paragraph 5 contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that TPM is a Delaware corporation with its principal place of business at 19 Hughes, Irvine, CA 92618. Defendants admit that TPM is a wholly-owned subsidiary of Teva USA. Defendants admit that TPM develops and markets

injectable drug products for sale and use throughout the United States, including this judicial district. Defendants deny the remaining allegations of paragraph 5.

6. Defendants admit that Teva USA is a Delaware Corporation with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. Defendants further admit that Teva USA is engaged in the manufacturing and sale of pharmaceutical products. Defendants admit that TPM is a wholly-owned subsidiary of Teva USA. Defendants deny the remaining allegations of paragraph 6.

7. Paragraph 7 contains conclusions of law for which no response is required. To the extent a response is required, Defendants state that they are without knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegation that "TPM's preparation and submission of ANDA No. 90-589 was completed in collaboration with, and oversight by, Teva USA and Teva Ltd." because the allegation is vague and undefined, and therefore Defendants deny the same.

JURISDICTION AND VENUE

8. Paragraph 8 contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that this Court has subject matter jurisdiction under sections 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202. Defendants deny the remaining allegations of paragraph 8.

9. Paragraph 9 contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that TPM and Teva USA are Delaware corporations. Defendants further admit that this Court has personal jurisdiction over them for the purpose of this action.

10. Paragraph 10 contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that this Court has personal jurisdiction over them for the purpose of this action. Defendants admit that they sell pharmaceutical products in the United States. Defendants deny the remaining allegations of paragraph 10, including any implication that TPM's product that is the subject of TPM's ANDA infringes any valid, enforceable claim of the '012 patent.

11. Paragraph 11 contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that venue for this action is proper in this Court.

BACKGROUND

12. Defendants admit that the approved label for the EpiPen® Auto-Injector specifies that the EpiPen® Auto-Injector is designed for immediate self-administration of a pre-determined dose of epinephrine in the emergency treatment of various allergic reactions, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis. Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 12, and therefore deny the same.

13. On information and belief, Defendants admit the allegations of paragraph 13.

14. Defendants admit that the United States Patent and Trademark Office ("USPTO") issued the '012 patent, attached to Plaintiffs' Complaint, on November 11, 2008, and that it is entitled "Automatic Injector," but specifically deny that the patent was duly and legally issued. Defendants further admit that Meridian is listed as the assignee on the face of the '012

patent and that according to the FDA's records the '012 patent will expire on September 11, 2025. Defendants deny any remaining allegations in paragraph 14.

15. Defendants admit that the '012 patent was listed in the FDA's Orange Book in connection with NDA No. 019-430. Defendants lack sufficient information from which to admit or deny the remaining allegations of paragraph 15, and therefore deny the same.

16. Paragraph 16 contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that TPM submitted ANDA No. 90-589 under 21 U.S.C. § 355(j)(2) before the '012 patent was listed in the Orange Book. Defendants further admit that after the '012 patent was listed in the Orange Book, TPM submitted a Paragraph IV certification that the '012 patent was invalid, unenforceable and/or not infringed. Defendants admit that TPM is seeking FDA approval to engage in the commercial manufacture, use and/or sale of TPM's Product prior to the expiration of the '012 patent. Defendants deny the remaining allegations of paragraph 16.

17. Defendants admit that by letter dated July 20, 2009, TPM notified Plaintiffs, as required by § 505(j)(2)(B)(ii) of the FDC Act, that it had submitted a Paragraph IV certification, in conjunction with previously filed ANDA No. 90-589, that the '012 patent was invalid, unenforceable and/or not infringed. Defendants deny the remaining allegations of paragraph 17.

18. Defendants admit that TPM's July 20, 2009, letter notified Plaintiffs that TPM had filed a Paragraph IV certification pursuant to § 505(j)(2)(A)(vii)(IV) of the FDCA and 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Defendants further state that the July 20, 2009 letter, along with a detailed statement of factual and legal bases, notified Plaintiffs as to why the '012 patent

is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, and/or sale of TPM's Product.

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 7,449,012 B2

19. Defendants repeat and incorporate by reference their answers to paragraphs 1-18.

20. Defendants admit the '012 patent, attached to Plaintiffs' Complaint as Exhibit A, lists Meridian as the Assignee. Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and, therefore, deny all remaining allegations of paragraph 20.

21. Defendants deny the allegations of paragraph 21, including any implication that TPM's Product that is the subject of TPM's ANDA infringes any valid, enforceable claim of the '012 patent.

22. Defendants admit that TPM submitted ANDA No. 90-589. Defendants admit that TPM submitted a paragraph IV certification to the '012 patent, to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale of its ANDA product prior to the expiration of the '012 patent. Defendants admit that filing an ANDA containing a Paragraph IV certification to an Orange Book listed patent vests this Court with subject matter jurisdiction with respect to that patent pursuant to 35 U.S.C. § 271(e). Defendants deny any remaining allegations of paragraph 22, including any implication that TPM's Product that is the subject of TPM's ANDA infringes any valid, enforceable claim of the '012 patent.

23. Defendants deny the allegations of paragraph 23, including any implication that TPM's Product that is the subject of TPM's ANDA infringes any valid, enforceable claim of the '012 patent.

24. Paragraph 24 contains conclusions of law for which no response is required. To the extent a response is required, Defendants state that they are without knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations that "Teva intends to engage in the manufacture, use, offer for sale, sale and/or importation of Teva's ANDA product, with its proposed labeling, immediately and imminently upon approval of ANDA No. 90-589," because the phrase "immediately upon approval" is vague and undefined, and therefore Defendants deny the same. Defendants deny all remaining allegations of paragraph 24.

25. Defendants deny the allegations of paragraph 25.

26. Defendants deny the allegations of paragraph 26.

27. Defendants deny the allegations of paragraph 27.

28. Defendants admit that the '012 patent was listed in the FDA's Orange Book after filing TPM filed its ANDA No. 90-589. Defendants admit that they were aware of the '012 patent after TPM filed its ANDA No. 90-589. Defendants deny the remaining allegations of paragraph 28.

29. Defendants deny the allegations of paragraph 29.

30. Defendants deny the allegations of paragraph 30.

COUNT II
DECLARATORY JUDGMENT

31. Defendants repeat and incorporate by reference its answers to paragraphs 1-30

32. Defendants state that they are without knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations that "if ANDA No. 90-589 is approved, Teva's ANDA product will be distributed in the United States by or through TPM and/or Teva

USA and their affiliates", and therefore Defendants deny the same. Defendants deny the remaining allegations of paragraph 32.

33. Defendants are without knowledge or information sufficient to form a belief as to the truth of Plaintiffs allegation as to what patients will do with TPM's Product, and therefore, deny the same. Defendants deny the remaining allegations of paragraph 33.

34. Defendants are without knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations that Defendants "plan to begin marketing, selling, and offering to sell Teva's ANDA product immediately after the FDA approves ANDA No. 90-589," because the term "immediately" is vague and undefined, and therefore Defendants deny the same. Defendants deny any remaining allegations of paragraph 34.

35. Defendants are without knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations that any manufacture, use, offer to sell, sale or importation of TPM's product "will begin immediately after the FDA approves ANDA No. 90-589" because the term "immediately" is vague and undefined, and therefore Defendants deny the allegation. Defendants deny any remaining allegations of paragraph 35.

36. Paragraph 36 contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations of paragraph 36.

37. Defendants deny the allegations of paragraph 37.

PRAYER FOR RELIEF

Defendants deny that Plaintiffs are entitled to any relief from the Court.

AFFIRMATIVE DEFENSES

First Affirmative Defense

TPM's product that is the subject of ANDA No. 90-589 has not infringed, does not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '012 patent.

Second Affirmative Defense

Claims of the '012 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112.

Third Affirmative Defense

Plaintiffs' Complaint fails to state a claim upon which relief may be granted.

Fourth Affirmative Defense

Teva Pharmaceuticals U.S.A., Inc. is not a proper party to this action.

Fifth Affirmative Defense

Any additional defenses or counterclaims that discovery may reveal.

DEFENDANTS' PRAYER FOR RELIEF

WHEREFORE, Defendants Teva Parenteral Medicines, Inc. and Teva Pharmaceuticals USA, Inc. respectfully request that the Court enter a Judgment and Order in its favor and against Plaintiffs King Pharmaceuticals, Inc. and Meridian Medical Technologies as follows:

A. For a declaration that TPM's product does not and will not infringe claims of U.S. Patent No. 7,449,012;

B. For a declaration that the claims of U.S. Patent No. 7,449,012 are invalid;

C. For an award of attorneys' fees pursuant to 35 U.S.C. § 285, other statutes or rules, or the general power of the Court;

D. For an award of costs;

E. Preliminarily and permanently enjoin Plaintiffs, its officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with Plaintiffs, from utilizing the patent-in-suit to block, hamper, hinder or obstruct FDA approval of TPM's proposed product;

F. Permanently enjoin Plaintiffs, its officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with Plaintiffs, from asserting or otherwise seeking to enforce the patent-in-suit against Defendants or anyone in privity with Defendants; and

G. For such other relief as the Court determines to be just and proper.

JURY DEMAND

Defendants Teva Parenteral Medicines, Inc. and Teva Pharmaceuticals USA, Inc. request a jury trial on all issues so triable.

Respectfully submitted,

John C. Phillips, Jr. Esq. (#110)
Brian E. Farnan, Esq. (#4089)
PHILLIPS, GOLDMAN & SPENCE, P.A.
1200 North Broom Street
Wilmington, DE 19806
Tel: (302) 655-4200
Fax: (302) 655-4210
jcp@pgslaw.com

OF COUNSEL
George C. Lombardi
Lynn MacDonald Ulrich
Ali I. Ahmed
WINSTON & STRAWN LLP
35 West Wacker Drive
Chicago, Illinois 60601
Tel: (312) 558-5600
Fax: (312) 558-5700

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